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<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b> <small>(use as many sheets as necessary)</small>				<b>Complete if Known</b>	
Sheet	1	of	4	Application Number	10/098,514
				Filing Date	March 11, 2002
				First Named Inventor	CHANG, Sandra P.
				Group Art Unit	1645
				Examiner Name	
				Attorney Docket Number	A-71339/RFT/TAL/NBC (464334-142)

<b>U.S. PATENT DOCUMENTS</b>					
Examiner Initials*	Cite No.*	U.S. Patent Document Number-Kind Code* (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
~	A1	4,745,051	05-1988	Smith et al.	
~	A2	6,270,800 B1	08-07-2001	Speaker et al.	
~	A3	6,420,523 B1	07-16-2002	Chang et al.	
	A4				
	A5				

<b>FOREIGN PATENT DOCUMENTS</b>					
Examiner Initials*	Cite No.*	Foreign Patent Document Country Code <sup>2</sup> Number <sup>3</sup> Kind Code <sup>4</sup> (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
~	B1	EP 0 329 257	08-1989	MICROGENESYS, INC.	RECEIVED
	B2				
	B3				
	B4				AUG 14 2003
	B5				
	B6				TECH CENTER 1000/2000

<b>OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS</b>					
Examiner Initials*	Cite No.*	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.			
~	C1	ANNON, "Human Clinical Trials of Plant Engineered as Vaccine are Successful; May Usher in New Era for Plant/Pharmaceutical Research," Am. Soc. Plant Phys. Newsletter 25(3):9 (1998)			
~	C2	BEVAN M, "Binary Agrobacterium vectors for plant transformation." Nucleic Acids Res. 1984 Nov 26;12(22):8711-21.			
~	C3	BURGHAUS PA, et al., "Immunization of Aotus nancymai with recombinant C terminus of Plasmodium falciparum merozoite surface protein 1 in liposomes and alum adjuvant does not induce protection against a challenge infection." Infect Immun. 1995 Sep;64(9):3614-9.			
~	C4	CHANG SP, et al., "A carboxyl-terminal fragment of Plasmodium falciparum gp195 expressed by a recombinant baculovirus induces antibodies that completely inhibit parasite growth." J Immunol. 1992 Jul 15;149(2):548-55.			
~	C5	CHANG SP, et al., "Generalized immunological recognition of the major merozoite surface antigen (gp195) of Plasmodium falciparum." Proc Natl Acad Sci U S A. 1989 Aug;86(16):6343-7.			
~	C6	CHANG SP, et al., "A recombinant baculovirus 42-kilodalton C-terminal fragment of Plasmodium falciparum merozoite surface protein 1 protects Aotus monkeys against malaria." Infect Immun. 1996 Jan;64(1):253-61.			
~	C7	CHEUNG et al. "Immunization with synthetic peptides of a Plasmodium falciparum surface antigen induces anti-merozoite antibodies," Proc. Natl. Acad. Sci. USA 83:8328 (1986).			
~	C8	DATLA, RSS, et al., "Improved high-level constitutive foreign gene expression in plants using an AMV RNA4 untranslated leader sequence," Plant Science 94(1/2):139 1993			

Examiner Signature	MARK MATARRO	Date Considered	2/17/04
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\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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Information Disclosure Statement by Applicant (use as many sheets as necessary)				Complete if Known	
Sheet	2	of	4	Application Number	10/098,514
				Filing Date	March 11, 2002
				First Named Inventor	CHANG, Sandra P.
				Group Art Unit	1645
				Examiner Name	
				Attorney Docket Number	A-71339/RFT/TAL/NBC (464334-142)

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OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS					
Examiner Initials*	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.			
~	C9	ELLIS, R.W., "New Technologies for Making Vaccines," in Vaccines, Plotkin, S.A. and Mortimer, Jr. E.A., eds., W.B. Saunders Co., Philadelphia (1988), Ch. 29, pp. 568-575			
~	C10	ESTRUCH, J.J. et al., "Transgenic plants: an emerging approach to pest control." Nat Biotechnol. 1997 Feb;15(2):137-41.			
~	C11	FISHER, DE and Guiltinan, MJ, "Rapid, Efficient Production of Homozygous Transgenic Tobacco Plants with Agrobacterium tumefaciens: A Seed-to-Seed Protocol." Plant Mol. Biol. Reporter 13(3):278-289 (1995)			
~	C12	FRALEY RT, et al., "Expression of bacterial genes in plant cells." Proc Natl Acad Sci U S A. 1983 Aug;80(15):4803-7.			
~	C13	FROMM, H. et al., "An octopine synthase enhancer element directs tissue-specific expression and binds ASF-1, a factor from tobacco nuclear extracts." Plant Cell. 1989 Oct;1(10):977-84.			
~	C14	GALLIE DR, et al., "The 5'-leader sequence of tobacco mosaic virus RNA enhances the expression of foreign gene transcripts in vitro and in vivo." Nucleic Acids Res. 1987 Apr 24;15(8):3257-73.			
~	C15	GOMORD V, et al., "The C-terminal HDEL sequence is sufficient for retention of secretory proteins in the endoplasmic reticulum (ER) but promotes vacuolar targeting of proteins that escape the ER." Plant J. 1997 Feb;11(2):313-25.			
~	C16	HALL et al. "Major surface antigen gene of a human malaria parasite cloned and expressed in bacteria," Nature 311:379 (1984).			
~	C17	HASEGAWA A, et al., "The complete sequence of soybean chlorotic mottle virus DNA and the identification of a novel promoter." Nucleic Acids Res. 1989 Dec 11;17(23):9993-10013.			
~	C18	HASELOFF J, et al., "Removal of a cryptic intron and subcellular localization of green fluorescent protein are required to mark transgenic Arabidopsis plants brightly." Proc Natl Acad Sci U S A. 1997 Mar 18;94(6):2122-7.			
~	C19	HAQ TA, et al., "Oral immunization with a recombinant bacterial antigen produced in transgenic plants." Science. 1995 May 5;268(5211):714-6.			
~	C20	HELLIWELL CA, and Gray JC. "The sequence surrounding the translation initiation codon of the pea plastocyanin gene increases translational efficiency of a reporter gene." Plant Mol Biol. 1995 Nov;29(3):621-6.			
~	C21	HERRERA et al. "Conserved Polypeptides of Plasmodium Falciparum as Malaria Vaccine Candidates?", Acta Leidensia, 60(1):107-110 (1991).			
~	C22	HERRERA et al. "Immunization of Aotus monkeys with Plasmodium falciparum blood-stage recombinant proteins." Proc. Natl. Acad. Sci. USA 87:4017 (1990).			
~	C23	HOLDER et al. "Immunization against blood-stage rodent malaria using purified parasite antigens," Nature 294:361 (1981).			
~	C24	HOLDER et al., "A hybrid gene to express protein epitopes from both sporozoite and merozoite surface antigens of Plasmodium falciparum," Parasitology, 97:373-382 (1988).			
~	C25	HOLDER, A.A. et al., "Immunization against Plasmodium falciparum with recombinant polypeptides produced in Escherichia coli." Parasite Immunology, 10(6):607-617 (1988).			
~	C26	HOLDER et al., "Primary Structure of the Precursor to the three major surface antigens of Plasmodium falciparum merozoite," Nature, 317:270-273 (1985).			
~	C27	HOLDER et al., "Processing of the precursor to the major merozoite surface antigens of Plasmodium falciparum," Parasitology, 94:199-208 (1987).			
~	C28	HUI et al. "Serum from Pf195 protected Aotus Monkeys Inhibit Plasmodium falciparum growth in Vitro," Exp. Parasitol. 64:519 (1987).			
~	C29	IANNACONE, R. et al., "Specific sequence modifications of a cry3B endotoxin gene result in high levels of expression and insect resistance." Plant Mol Biol. 1997 Jun;34(3):485-96.			

Examiner Signature	MARK NAVARRO	Date Considered	2/17/04
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INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT

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Sheet 3 of 4

10/098,514

March 11, 2002

CHANG, Sandra P.

1645

Examiner Name

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Attorney Docket Number

## OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume/issue number(s), publisher, city and/or country where published.
~	C30	JOBLING SA, and GEHRKE L. "Enhanced translation of chimaeric messenger RNAs containing a plant viral untranslated leader sequence." Nature. 1987 Feb 12-18;325(6105):622-5.
~	C31	JOSHI RL, et al., "BSMV genome mediated expression of a foreign gene in dicot and monocot plant cells." EMBO J. 1990 Sep;9(9):2663-9.
~	C32	KNAPP, B. et al. "A histidin alanine rich recombinant antigen protects aotus monkeys from P. falciparum infection." Behring Inst. Mitt. 82:349-59 (1988).
~	C33	KOZIEL MG, et al., "A cauliflower mosaic virus promoter directs expression of kanamycin resistance in morphogenic transformed plant cells." J Mol Appl Genet. 1984;2(6):549-62.
~	C34	KUMAR S, et al., "Immunogenicity and efficacy in aotus monkeys of four recombinant Plasmodium falciparum vaccines in multiple adjuvant formulations based on the 19-kilodalton C terminus of merozoite surface protein 1." Infect Immun. 2000 Apr;68(4):2215-23.
~	C35	LEW et al. "A protective monoclonal antibody recognizes a linear epitope in the precursor to the major merozoite antigens of Plasmodium chabaudi adami." Proc. Natl. Acad. Sci. USA 86:3768 (1989).
~	C36	LOCHER CP, et al., "Plasmodium falciparum: gp195 tripeptide repeat-specific monoclonal antibody inhibits parasite growth in vitro." Exp Parasitol. 1996 Oct;84(1):74-83.
~	C37	LUMBRERAS, V. et al., "The use of an alternative promoter in the Arabidopsis thaliana HMG1 gene generates an mRNA that encodes a novel 3-hydroxy-3-methylglutaryl coenzyme A reductase isoform with an extended N-terminal region." Plant J. 1995 Oct;8(4):541-9.
~	C38	MA JK, et al., "Generation and assembly of secretory antibodies in plants." Science. 1995 May 5;268(5211):716-9.
~	C39	MAITI IB, and Shepherd RJ. "Isolation and expression analysis of peanut chlorotic streak caulimovirus (PCISV) full-length transcript (FL1) promoter in transgenic plants." Biochem Biophys Res Commun. 1998 Mar 17;244(2):440-4. Errata appears in Biochem Biophys Res Commun. 1998 Jul 9;248(1):210.
~	C40	MASON HS, et al., "Expression of hepatitis B surface antigen in transgenic plants." Proc Natl Acad Sci U S A. 1992 Dec 15;89(24):11745-9.
~	C41	MITRA A, et al., "A Chlorella virus gene promoter functions as a strong promoter both in plants and bacteria." Biochem Biophys Res Commun. 1994 Oct 14;204(1):187-94.
~	C42	MAJARIAN et al. "Passive Immunization against Murine Malaria with an IgG3 Monoclonal Antibody." J. Immunol. 132:3131 (1984).
~	C43	MOFFAT AS. "Exploring transgenic plants as a new vaccine source." Science. 1995 May 5;268(5211):658-660.
~	C44	MURPHY, V.F. et al., "Expression of hybrid malaria antigens in insect cells and their engineering for correct folding and secretion." Parasitology, 100 pt. 2:177-183 (1990).
~	C45	ODINK K.G. et al., "Expression of cloned cDNA for a major surface antigen of Plasmodium falciparum merozoite." FEBS Lett. (1984) 108-12.
~	C46	OHME-TAKAGI, M. et al. "The effect of sequences with high AU content on mRNA stability in tobacco." Proc Natl Acad Sci U S A. 1993 Dec 15;90(24):11811-5.
~	C47	PATARROYO et al. "A synthetic vaccine protects humans against challenge with asexual blood stages of Plasmodium falciparum malaria." Nature 332:158 (1988).
~	C48	PATARROYO et al. "Induction of protective immunity against experimental infection with malaria using synthetic peptides." Nature 328:629 (1987).

Examiner Signature	MARIE NARAYAN	Date Considered	2/17/04
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